

10-5-88

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

Antimicrobial Program Branch

IN 07-28-88

OUT 09/26/88

Reviewed By Srinivas Gowda ^{WEL} _{10/5/88} Date 09/26/88

EPA Reg. No. or File Symbol 8383-3

EPA Petition or EUP No. None

Date Division Received 07-15-88

Type Product(s): Hospital Disinfectant

MRID No(s) 408317-01

Product Mgr. No. 32 (Kempter)

Product Name(s) Permacide Brand Ristex Germicidal/Disinfectant

Company Name (s) Sporicidin International

Submission Purpose Amendment to add additional virucidal claim
(Vaccinia) with data, label, and collateral
labeling

Chemical & Formulation Ready-to-use, liquid

Active Ingredient (s): %

Phenol.....1.41

Sodium Phenate.....0.24

Sodium Borate.....0.47

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200.00 Introduction

200.1 Use (s)

Proposed labels are attached.

200.2 Background Information

The submission received 07-15-88, is an amendment to add an additional virucidal claim against Vaccinia virus with efficacy data, revised labelings and collateral labelings.

201.0 Data Summary

201.1 Brief Description of Test

Reports of Virucidal Tests by Philip R. Roane, Integrity Bioservices, Inc., 12280 Wilkens Avenue - Rockville, MD 20852, dated 06-30-88 (MRID No. 408317-01)

201.2 Test Summaries

Virucidal Tests:

1. Method: Modified A.O.A.C. Use-Dilution Method/DIS/TSS-7 Enclosure.
2. Modifications: An aqueous virus suspension (0.5 ml) containing 10% fetal bovine serum was dried on replicate 60 mm petridishes. The quantitative survival of virus after drying was expressed as "virus control". The disinfectant solution was dispensed in accordance with the directions for application such that 0.5 ml was delivered to the surface of each of the petridish and allowed to stand for 3 minutes.
3. Samples: Pump spray

<u>Batch No.</u>	<u>Mfg. Date</u>	<u>Test Dates</u>
D2783	04-27-88	06-16-88 to 06-23-88
J0470	10-04-87	"
4. Dilution: Undiluted
5. Exposure: 3 minutes at 20°C
6. Recovery Medium/Neutralizer/Diluent:

EMEM 98% & FBS 2%/Lethen broth

Neutralizer Time: 10 minutes at 20°C.
7. Incubation : 7 days at 37°C

8. Test Virus Host System: Vero
9. Assay System for Virus Recovery: Cytopathic effect
10. Drying Time and Temperature: 2 hours at 20°C
11. Method for Estimating 50 Per Cent end-point: Reed-Muench.
12. Test Virus: Vaccinia virus (Strain KB-2)
13. Test Results

<u>ID-50 or LD-50 (-log 10)</u>					
<u>Test Virus</u>	<u>Batch No.</u>	<u>Virus Control</u>	<u>Virus + Disinf.</u>	<u>Toxicity Control</u>	<u>Virus Inacti.</u>
Vaccinia	D2783	7.5	2.5	2.5	5.0
	J0470	7.5	2.5	2.5	5.0

15. Conclusions: Satisfactory performance vs Vaccinia virus as an undiluted pump spray in the presence of 10% FBS on moderately soiled, hard, non-porous surfaces for a contact time of 3 minutes at 20°C.

Page _____ is not included in this copy.

Pages 4 through 9 are not included.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
 - ☐ Identity of product impurities.
 - ☐ Description of the product manufacturing process.
 - ☐ Description of quality control procedures.
 - ☐ Identity of the source of product ingredients.
 - ☐ Sales or other commercial/financial information.
 - ☒ A draft product label.
 - ☐ The product confidential statement of formula.
 - ☐ Information about a pending registration action.
 - ☐ FIFRA registration data.
 - ☐ The document is a duplicate of page(s) _____.
 - ☐ The document is not responsive to the request.
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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EFFICACY REVIEW-II

Antimicrobial Program Branch

EPA Reg. No. or File Symbol 8383-3
Date Division Received 07-15-88
MRID No.(s). 408317-01
Product Manager No. PM-32 (Kempter)
Product Name Permacide Brand Ristex Germicidal/Disinfectant
Company Name Sporicidin International

202.0 Recommendations

202.1 Efficacy Supported by the Data

The submitted virucidal data are adequate to support effectiveness of the product as a virucide against Vaccinia virus when used as an undiluted pump spray to thoroughly wet moderately soiled, hard, non-porous surfaces in the presence of 10% Fetal Bovine Serum for a contact time of 3 minutes at 20°C.

203.0 Labeling

No adverse comments

204.0 Collateral labeling

No adverse comments